DEPARTMENT OF HEALTH AND HUMAN SERVICES

M3679R

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

April 26, 2000

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**
Ref. KAN-2000-014

Mr. Richard K. Rounsborg, President
Med-Pro Inc.
210 E 4th Street
Lexington, NE 68850

Dear Mr. Rounsborg:

During an inspection of your human drug repacking facility located in Lexington, NE, conducted on February 8-11, 2000, our investigator found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for human drugs (21 CFR, Part 210 and 211). These deviations cause human drugs being repacked at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Significant deviations include but are not limited to the following:

- Failure to establish written procedures to assure correct Master Batch Records are used when different drug dosage forms of the same product are produced [21 CFR 211.100(a) and 211.186]

- Failure to verify product against the Master Batch Record [21 CFR 211.100(b)];

- Failure to document investigations during product record review and include the conclusion and follow-up [21 CFR 211.192];

- Failure to have an adequate number of qualified personnel to perform and supervise the manufacturing, processing, packing, or holding of each drug [21 CFR 211.25(c)];

- Failure to have master production records independently checked, dated, and signed by a second person [21 CFR 211.186(a)];

- Failure to monitor printing devices associated with imprinting labeling to assure that imprinting conformed with print specified in the batch production record [21 CFR 211.122(h)];

[redacted]

- Failure to have actual yields performed by one person and independently verified by a second person [21 CFR 211.103];

- Failure to perform evaluations at least annually, on the quality standards of each drug product [21 CFR 211.180(e)(1)]; and

- Failure to conduct Current Good Manufacturing Practice training on a continuous basis [21CFR 211.25]

The above is not an all-inclusive list of deficiencies at your facility. As a repacker of human drugs, you are responsible for assuring that your overall operation and the products you repack and distribute are in compliance with the law.

You should take prompt action to correct these violations and establish appropriate controls and/or procedures that will prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Your response to the above observations dated February 22, 2000 was received and appears adequate. We would like a response to this letter within fifteen (15) days addressing any controls and procedures implemented since your February 22, 2000 correspondence. All the items stated in your response will be verified during our next inspection. If you have any further questions or concerns, you should address them to Monica R. Maxwell, Compliance Officer, at the above address.

Sincerely,

John W. Thorsky
Acting District Director
Kansas City District